AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application. Where claims have been amended, deletions are indicated by ~~strikethrough~~, and additions are indicated by underlining:

In the claims:

Claims 1 through 25 are canceled.

26. (Currently Amended) Apparatus for performing a medical procedure within a hollow body organ of tortuous or unpredictably supported anatomy, the apparatus comprising:

an overtube having a flexible state that facilitates insertion of the overtube into the hollow body organ, and a rigid state wherein the overtube resists bending forces exerted on the overtube;

a mechanism selectively operable to reversibly transition the overtube between the flexible and rigid states, wherein at least a portion of the overtube is configured to be manipulated from outside the hollow body organ;

a first catheter having a flexible tube with a distal region configured for insertion through the overtube and into the hollow body organ;

a tissue engaging assembly disposed on the distal region of the first catheter, the tissue engaging assembly defining a first tissue contact point; and

an anchor delivery system adapted to deliver an anchor assembly and secure a tissue fold, the anchor delivery system comprising a flexible delivery catheter having an internal lumen and being adapted for insertion into the hollow body organ, the flexible delivery catheter having a bending section adapted to transition from a first position in which the bending section is generally aligned with a longitudinal axis of a proximal portion of the flexible delivery catheter, to a second position in which the bending section is generally transverse to the longitudinal axis of the proximal portion of the flexible catheter, with a distal end of the bending section being connected to the tissue engaging

assembly of the first catheter, and the flexible delivery catheter having a needle adapted to transition from a first position in which the needle is substantially completely retained within the flexible delivery catheter, to a second position in which a distal portion of the needle extends from a distal end of the flexible delivery catheter for transverse passage through the tissue fold, the flexible delivery catheter further comprising a flexible push rod that is slidably disposed within an internal lumen of the needle and that is adapted to deploy the anchor assembly from the distal portion of the needle.

27. (Original) The apparatus of claim 26, wherein at least one section of the overtube is adapted to remain in the flexible state upon transition of the overtube to the rigid state.

28. (Original) The apparatus of claim 26, wherein at least one section of the overtube comprises varied rigidity relative to a different section of the overtube when the overtube is disposed in the rigid state.

29. (Original) The apparatus of claim 26, wherein at least one section of the overtube comprises varied flexibility relative to a different section of the overtube when the overtube is disposed in the flexible state.

30-31. (Cancelled).

32. (Previously presented) The apparatus of claim 26, further comprising:

a second tissue contact point disposed at a location initially proximal of, or in line with, the first tissue contact point.

33. (Previously presented) The apparatus of claim 32, further comprising:

a tissue approximation device for moving the first tissue contact point to a position proximal of the second tissue contact point to form a tissue fold.

34. (Previously presented) The apparatus of claim 33 further comprising a third tissue contact point disposed at a location initially proximal of, or in line with, the first tissue contact point, wherein the tissue approximation device for moving moves the first tissue contact point to a position proximal of the third tissue contact point to form the tissue fold, so that the second and third tissue contact points are disposed on opposing sides of the tissue fold.

35. (Previously presented) The apparatus of claim 34, wherein the tissue approximation device for moving linearly displaces the first tissue contact point relative to the second and third tissue contact points.

36 – 39. (Cancelled).

40. (Previously presented) The apparatus of claim 26, wherein the anchor assembly is configured for delivery through the needle.

41. (Previously presented) The apparatus of claim 26, wherein the tissue engaging assembly is configured to engage mucosa, thereby defining the first tissue contact point.

42. (Previously presented) The apparatus of claim 26, wherein the tissue engaging assembly is configured to engage muscularis, thereby defining the first tissue contact point.

43. (Previously presented) The apparatus of claim 26, wherein the tissue engaging assembly is configured to engage serosa, thereby defining the first tissue contact point.

44. (Previously presented) The apparatus of claim 26, wherein the tissue fold comprises serosa-to-serosa tissue contact and the anchor assembly is adapted to secure

the serosa-to-serosa tissue contact.

45. (Currently Amended) Apparatus for performing a medical procedure within a hollow body organ, the apparatus comprising:

an overtube having a steerable distal region;

a first catheter having a flexible tube with a distal region configured for insertion through the overtube and into the hollow body organ;

a tissue engaging assembly disposed on the distal region of the first catheter, the tissue engaging assembly defining a first tissue contact point; and

an anchor delivery system adapted to deliver an anchor assembly and secure a tissue fold, the anchor delivery system comprising a flexible delivery catheter having an internal lumen, the flexible delivery catheter having a bending section adapted to transition from a first position in which the bending section is generally aligned with a longitudinal axis of a proximal portion of the flexible delivery catheter, to a second position in which the bending section is generally transverse to the longitudinal axis of the proximal portion of the flexible catheter, with a distal end of the bending section being connected to the tissue engaging assembly of the first catheter, and the flexible delivery catheter having a needle adapted to transition from a first position in which the needle is substantially completely retained within the flexible delivery catheter, to a second position in which a distal portion of the needle extends from a distal end of the flexible delivery catheter for transverse passage through the tissue fold, the flexible delivery catheter further comprising a flexible push rod that is slidably disposed within an internal lumen of the needle and that is adapted to deploy the anchor assembly from the distal portion of the needle.

46. (Previously presented) The apparatus of claim 45, wherein the anchor assembly is configured for delivery through the needle.

47. (Previously presented) The apparatus of claim 45, further comprising an endoscope movably disposed within a lumen of said overtube.

48. (Currently Amended) Apparatus for performing a medical procedure within a hollow body organ, the apparatus comprising:

an overtube having a steerable distal region;

an endoscope movably disposed within a lumen of said overtube;

a first catheter having a flexible tube with a distal region configured for insertion through the overtube and into the hollow body organ;

a tissue engaging assembly disposed on the distal region of the first catheter, the tissue engaging assembly defining a first tissue contact point; and

a flexible delivery catheter extending through said overtube and having an internal lumen, the flexible delivery catheter having a bending section adapted to transition from a first position in which the bending section is generally aligned with a longitudinal axis of a proximal portion of the flexible delivery catheter, to a second position in which the bending section is generally transverse to the longitudinal axis of the proximal portion of the flexible catheter, with a distal end of the bending section being connected to the tissue engaging assembly of the first catheter, and the flexible delivery catheter having a needle adapted to transition from a first position in which the needle is substantially completely retained within the flexible delivery catheter, to a second position in which a distal portion of the needle extends from a distal end of the flexible delivery catheter for transverse passage through the tissue fold, the flexible delivery catheter further comprising a flexible push rod that is slidably disposed within an internal lumen of the needle and that is adapted to deploy the anchor assembly from the distal portion of the needle.

49. (Previously presented) The apparatus of claim 48, further comprising an anchor assembly configured for delivery through the needle.

REMARKS

Claims 26-29, 32-35, and 40-49 were pending in the application. By this amendment, claims 26, 45, and 48 have been amended. No claims have been added or cancelled. Accordingly, claims 26-29, 32-35, and 40-49 remain pending.

The following remarks are in response to the rejections of claims and other matters set forth in the Office Action.

Claims Rejected Under 35 U.S.C. § 103

Claims 26-29, 32-35, and 40-49 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Suzuki et al. (US 2002/0111534) in view of Cerier (US 2004/0133238) and Jaffe (US 2002/0161281). Without acceding to any of the Examiner's stated grounds for rejecting the claims, Applicants respond as follows.

To establish a prima facie case of obviousness under 35 U.S.C. § 103(a) in view of a reference or combination of references, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference(s) must teach or suggest all the claim limitations. Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. Finally, in determining the differences between the prior art and the claims, the question under 35 U.S.C. § 103(a) is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.

Each of the independent claims – claims 26, 45, and 48 – recites an apparatus for performing a medical procedure having, *inter alia*, an overtube, a first catheter, and a flexible delivery catheter having a needle and being adapted to deliver an anchor assembly and secure a tissue fold. By this amendment, each of these claims has been

amended to recite the following limitations concerning a bending section of the flexible delivery catheter being connected to the first catheter:

> with a distal end of the bending section being connected to the tissue engaging assembly of the first catheter.

Support for these features is provided throughout the specification such as, for example, at paragraphs 0082-86 and at FIGS. 3A-E. For example, paragraph 0084 states the following in reference to FIG. 3D, which is reproduced below (emphasis added):

> Referring to FIG. 3D, additional proximal movement of actuator 17 causes flexible tubes 13 and 14 to buckle at bendable sections 25 and 26. *Hinge assembly 20 transmits force applied to flexible tube 13 via control wire 19 and actuator 17 to the distal tip 24.*

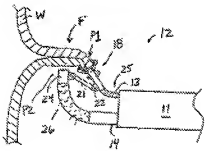
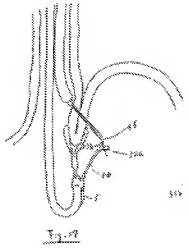


FIG. 3D

The Suzuki publication describes an apparatus that includes a sheath 84, and a first endoscope 2 and second endoscope 6 insertable through the sheath 84. (See Suzuki, Fig. 1, paragraphs 0038-39). A holding device 11 that includes a sheath 14 ("first catheter") extends through the first endoscope. The second endoscope 6 includes a needle tool 40 that has a sheath 42 ("flexible delivery catheter"), a needle 44, and a suture 46 inserted slidably in the lumen of the needle 44. (Suzuki, Figs. 7-9, paragraph 0044). As explained in the Office Action (at pg. 3): "A distal portion of the flexible delivery catheter is then bent toward the first tissue contact point ([0054]; Figure 17)." Figure 17 from the Suzuki publication is reproduced below, and shows a distal portion of the needle tool 40 directed toward the tissue being held by the holding device 11. However, it is clear that the distal portion of the needle tool 40 (the "flexible delivery catheter") **is not**

connected to the sheath 14 of the holding device 11 (the "first catheter"), as recited in independent claims 26, 45, and 48, as amended.



As a result, the Suzuki apparatus does not include the recited "distal end of the bending section being connected to the tissue engaging assembly of the first catheter."

The Cerier and Jaffe publications do not provide any teaching or suggestion that corrects these deficiencies. Neither of the devices described in those publications includes a first catheter connected to a distal portion of a flexible delivery catheter. Nor is there any teaching or suggestion in either of the Suzuki, Cerier, or Jaffe publications (or the art in general) that any of the disclosed devices should be modified to include a first catheter connected to a distal portion of a flexible deliver catheter, as recited in claims 26, 45, and 48.

Accordingly, because at least these limitations recited in claims 26, 45, and 48 are not taught or suggested by the Suzuki, Cerier, or Jaffe publications, the Office Action fails to establish a prima facie case of obviousness of claims 26, 45, and 48 or the claims dependent therefrom. Applicants respectfully request withdrawal of the rejections of claims 26-29, 32-35, and 40-49.

Amendment and/or cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented,

but rather as an attempt to expedite allowance and issuance of the currently pending claims. No new matter has been added.